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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

Richard P. Carter,

Plaintiff,

v.

Pfizer, Inc.,

Defendant.

Case No. _____

COMPLAINT FOR DAMAGES

1. **Unfair and Deceptive Trade Practices (Unfairness)**
2. **Unfair and Deceptive Trade Practices (Fraud)**
3. **Unfair and Deceptive Trade Practices (Unlawfulness)**
4. **Strict Liability – Defective Design**
5. **Strict Liability – Failure to Warn**
6. **Failure to Test**
7. **Negligence**
8. **Gross Negligence**
9. **Negligence Per Se**
10. **Breach of Express Warranty**
11. **Breach of Implied Warranty**
12. **Fraudulent Misrepresentation and Concealment**
13. **Negligent Misrepresentation and Concealment**
14. **Fraud and Deceit**
15. **Willful, Wanton, and Malicious Conduct**
16. **Unjust Enrichment**

DEMAND FOR JURY TRIAL

1 Plaintiff, Richard P. Carter, individually alleges:

2 **I. BACKGROUND**

3 This is an action for personal injuries and damages suffered by Plaintiff Richard P. Carter
4 (“Plaintiff”) as a direct and proximate result of Pfizer, Inc.’s (“Pfizer”) negligent and wrongful
5 conduct in connection with the design, development, manufacture, testing, packaging, promoting,
6 marketing, distribution, labeling, and/or sale of sildenafil citrate tablets sold under the brand name
7 Viagra® (“Viagra”).

8 **II. JURISDICTION AND VENUE**

9 1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the
10 amount in controversy exceeds \$75,000.00, exclusive of interest and costs, and because Pfizer is a
11 citizen of a state other than the state in which Plaintiff is a citizen.

12 2. The Parties conferred regarding jurisdiction and venue before filing in the Northern
13 District of California.

14 3. Intradistrict Assignment. Pursuant to Local Rule 3-5, Plaintiff asserts that the
15 particular location or division appropriate for this case is the San Francisco Division and the
16 Honorable Judge Richard Seeborg. On December 11, 2015, a petition was filed with the Judicial
17 Panel on Multidistrict Litigation (JPML) seeking coordination of cases involving individuals who
18 used Viagra and suffered melanoma injuries. The petition sought consolidation before this
19 Honorable Court in the Northern District of California. *See In re Viagra Products Liability*
20 *Litigation*, MDL No. 2691. The petition is fully briefed and unopposed by the Defendant and all
21 other interested parties. The JPML will hear oral arguments on March 31, 2016.

22 4. Related Viagra actions are pending in this and other federal judicial districts across
23 the country. The parties have stipulated to stay all activity until the JPML issues an order ruling
24 Plaintiffs’ petition seeking coordination. In view of this pretrial cooperation, Plaintiff is filing
25 this Complaint in the Northern District of California. Plaintiff reserves the right to assert all of
26 his legal claims under Georgia substantive law in that Plaintiff resides in the County of Glynn,
27 State of Georgia (hereinafter “Plaintiff’s Home Forum”). For purposes of remand and trial, venue
28 is proper in the Plaintiff’s Home Forum, the United States District Court for the Southern District

1 of Georgia.

2 5. Plaintiff's Home Forum is the United States District Court for the Southern District of
3 Georgia. Plaintiff is domiciled in Georgia. Plaintiff was prescribed Viagra in Georgia, he was
4 exposed to Viagra in Georgia, and he sustained his injuries in Georgia.

5 6. Venue in this judicial district is proper under 28 U.S.C. § 1391(a) as Defendant is
6 subject to this Court's personal jurisdiction.

7 7. At all times herein mentioned, Pfizer conducted, and continues to conduct, a
8 substantial amount of business activity in this judicial district and the Plaintiff's Home Forum.
9 Pfizer is registered to conduct business in this district, and engaged in interstate commerce when
10 it advertised, promoted, supplied, and sold pharmaceutical products, including Viagra, to
11 distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general
12 public, deriving substantial revenue in California, Plaintiff's Home Forum, and throughout the
13 United States.

14 **III. PARTIES**

15 8. Plaintiff, Richard P. Carter, is and was at all relevant times an adult resident citizen of
16 the United States, residing in the County of Glynn, State of Georgia. The named Plaintiff's Home
17 Forum is proper for purposes of remand, transfer, and venue.

18 9. Defendant Pfizer, Inc. is a Delaware corporation with its principal place of business at
19 235 East 42nd Street, New York, New York, 10017. Defendant's registered agent is C T
20 Corporation System, 818 West Seventh Street, Suite 930, Los Angeles, California 90017.

21 10. At all relevant times Pfizer, including its owners, employees, parent companies,
22 subsidiaries, affiliates, and agents, were engaged in the business of designing, testing,
23 manufacturing, packaging, marketing, distributing, promoting, selling, and providing warnings
24 and/or instructions for Viagra in California, Plaintiff's Home Forum, and throughout the United
25 States.

26 **IV. FACTS**

27 **A. Background**

28 11. On March 27, 1998, the U.S. Food and Drug Administration approved a new drug

1 application (“NDA”) from Pfizer Pharmaceuticals Production Corporation Limited for the
2 manufacture and sale of sildenafil citrate.

3 12. Sildenafil citrate, sold under the brand name Viagra, is an oral tablet prescribed to
4 men with erectile dysfunction.

5 13. Erectile dysfunction is the medical designation for a condition in which a man cannot
6 achieve or maintain an erection sufficient for satisfactory sexual activity. Since achieving and/or
7 maintaining an erection involves the brain, nerves, hormones, and blood vessels, any condition
8 that interferes with any of these functional areas of the body may be causally related to an
9 individual’s erectile dysfunction. These problems become more common with age, but erectile
10 dysfunction can affect a man at any age.

11 14. Viagra treats erectile dysfunction by inhibiting the secretion of phosphodiesterase
12 type 5 (“PDE5”), an enzyme responsible for the degradation of cyclic guanosine monophosphate
13 (“cGMP”). When the cGMP is not degraded by the PDE5, smooth muscles in the corpus
14 cavernosum relax; this, in turn, permits an inflow of blood to the corpus cavernosum, creating an
15 erection.

16 15. The National Institutes of Health estimate that erectile dysfunction affects as many as
17 thirty million men in the United States.¹

18 **B. Prevalence of Viagra in Market**

19 16. In its 2013 Annual Report, Pfizer states that it accumulated revenue exceeding
20 \$1,800,000,000 from worldwide sales of Viagra. This statistic is particularly significant in light of
21 the fact that Pfizer lost exclusivity of Viagra throughout Europe in 2013, which in itself led to a
22 drop in profits from the previous calendar year.

23 17. Viagra holds approximately 45% of the United States market share for erectile
24 dysfunction medications.²

25 18. Pfizer estimates that Viagra has been prescribed to more than 35 million men
26

27 ¹ NIH Consensus Development Panel on Impotence (July 7, 1993).

28 ² Jacques Wilson, *Viagra: The Little Blue Pill That Could*, CNN, Mar. 27, 2013, available at:
<http://www.cnn.com/2013/03/27/health/viagra-anniversary-timeline/index.html>.

1 worldwide.³

2 19. In 2012 alone, physicians wrote approximately eight million prescriptions for
3 Viagra.⁴

4 **C. Pfizer's Knowledge of Defect**

5 20. In a 1997 FDA Carcinogenicity Assessment Committee Report, rats were given 60
6 mg/kg per day of sildenafil, a dose less than the maximum dose approved for human
7 consumption, and an increased proliferation in thyroid follicular cells was observed.⁵ Evidence
8 from a separate study suggested an alternative explanation of increased proliferation, however,
9 this study was conducted with a different dosage and did not apply the 60 mg/kg dosage given to
10 rats that experienced a proliferation of thyroid follicular cells.

11 21. In the same FDA report, mice studies were not carried to completion due to increased
12 mortality.⁶ Groups receiving a 30 mg/kg dose of sildenafil were near or below 20 percent
13 survival and were terminated after 13-15 months of treatment. Groups receiving a 10 mg/kg dose
14 of sildenafil were near 20 percent survival and were terminated after 19-22 months of treatment.

15 22. Unbeknownst to most Viagra users, recent studies have shown that the cellular
16 activity providing the mechanism of action for Viagra may also be associated with the
17 development and/or exacerbation of melanoma.

18 23. The American Cancer Society states that melanoma is "the most serious type of skin
19 cancer."⁷

20 24. According to the National Cancer Institute, part of the National Institutes of Health,
21 melanoma is more likely than other skin cancers to spread to other parts of the body, thereby
22 causing further tissue damage and complicating the potential for effective treatment and

23 ³ Hilary Stout, *Viagra: The Thrill That Was*, N.Y. TIMES, June 5, 2011, available at:
24 <http://query.nytimes.com/gst/fullpage.html?res=9B06E3DF173FF936A35755C0A9679D8B63>.

25 ⁴ Wilson, *supra* note 4.

26 ⁵ *Carcinogenicity Assessment Report and FDA-CDER Rodent Carcinogenicity Database*
27 *Factsheet*, NDA #20-895 (1997), available at:
28 http://www.accessdata.fda.gov/drugsatfda_docs/nda/98/viagra/carcin_rep.pdf.

⁶ *Id.*

⁷ American Cancer Society, *Skin Cancer Facts*, last revised March 19, 2014, available at:
<http://www.cancer.org/cancer/cancercauses/sunanduvexposure/skin-cancer-facts>.

1 eradication of the cancerous cells.⁸

2 25. Several studies have linked the mechanism of action for Viagra to cell mutation
3 cultivating melanomagenesis, or the creation of melanocytes which develop into melanoma.

4 26. A study published in 2011 found that treatment with Viagra can promote melanoma
5 cell invasion.⁹ Specifically, by inhibiting PDE5, Viagra mimics an effect of gene activation and
6 therefore may potentially function as a trigger for the creation of melanoma cells.

7 27. A 2012 study published in the Journal of Cell Biochemistry also found that PDE5
8 inhibitors were shown to promote melanin synthesis,¹⁰ which may exacerbate melanoma
9 development.¹¹

10 28. On April 7, 2014, an original study (“the JAMA study”) was published on the website
11 for the *Journal of the American Medical Association Internal Medicine* which, in light of the
12 previous studies, sought to examine the direct relationship between sildenafil use and melanoma
13 development in men in the United States.¹² The JAMA study was published in the journal’s June
14 2014 edition.

15 29. Among 25,848 participants, the JAMA study reported that recent sildenafil users at
16 baseline had a significantly elevated risk of melanoma, with a “hazard ratio” of 1.84; in other
17 words, the study participants who had recently used sildenafil exhibited an 84% increase in risk
18 of developing or encouraging invasive melanoma. The study also reported that individuals that
19 had used Viagra at any time in the past (“ever use”) had an even greater significant elevated risk
20 of melanoma, with a “hazard ratio” of 1.92.¹³

21
22 ⁸ National Cancer Institute, *Types of Skin Cancer*, last updated Jan. 11, 2011, available at:
<http://www.cancer.gov/cancertopics/wyntk/skin/page4>.

23 ⁹ I. Arozarena, et al., *Oncogenic BRAF Induces Melanoma Cell Invasion by Downregulating The*
cGMP-Specific Phosphodiesterase PDE5A, 19 CANCER CELL 45 (2011).

24 ¹⁰ X Zhang, et al., *PDE5 Inhibitor Promotes Melanin Synthesis Through the PKG Pathway in*
B16 Melanoma Cells, 113 J. CELL BIOCHEM. 2738 (2012).

25 ¹¹ F.P. Noonan, et al., *Melanoma Induction by Ultraviolet A But Not Ultraviolet B Radiation*
Requires Melanin Pigment, 3 NATURE COMMUNICATIONS 884 (2012).

26 ¹² Wen-Qing Li, Abrar A. Qureshi, Kathleen C. Robinson, & Jiali Han, *Sildenafil Use and*
27 *Increased Risk of Incident Melanoma in U.S. Men: A Prospective Cohort Study*, 174 JAMA
INTERNAL MEDICINE 964 (2014).

28 ¹³ *Id.*

D. Consumer Expectations

30. Since Viagra's FDA approval in 1998, Pfizer has engaged in a continuous, expensive, and aggressive advertising campaign to market Viagra to men worldwide as a symbol of regaining and enhancing one's virility.

31. Pfizer has engaged in increasingly aggressive marketing techniques and strategies to promote the use of Viagra in the face of increasing pharmaceutical competition. By means of demonstration, a 2004 article in The Chicago Tribune cited industry reports stating that Pfizer spent "tens of millions of dollars each month on direct-to-consumer advertising []."¹⁴

32. Pfizer has also been criticized by regulators, physicians and consumer groups for its attempts to target younger men in its advertising. Doctors and federal regulators stated that "such ads sen[t] a confusing message to patients who might really benefit from the drug."¹⁵

33. While designing and formulating Viagra, Pfizer discovered or should have discovered that the drug's mechanism of action, the inhibition of PDE5, also presented a significant risk of development and/or exacerbation of melanoma.

34. Despite these significant findings, Pfizer has made no efforts in its ubiquitous Viagra advertisements to warn users about the potential risk of developing melanoma that has been scientifically linked to its drug.

35. Members of the general public had no plausible means through which they could have discovered the significant risk of melanomagenesis associated with PDE5 inhibition.

36. Prescribing physicians would not have had the same level of access to the research and development conducted by Pfizer prior to its decision to manufacture Viagra for general public use.

37. Pfizer failed to communicate to the general public that the inhibition of PDE5 inherently necessary to the efficacy of Viagra would also present a significant risk of one's

¹⁴ Bruce Japsen, *Viagra's 2 Rivals Grab Market Share In A Year*, CHICAGO TRIBUNE, Sept. 23, 2004, available at http://articles.chicagotribune.com/2004-09-23/business/0409230283_1_viagra-erectile-levitra.

¹⁵ Bruce Japsen, *Toned-Down Advertising Credited for Viagra Gains*, CHICAGO TRIBUNE, Feb. 8, 2007, available at http://articles.chicagotribune.com/2007-02-08/business/0702080063_1_viagra-erectile-pfizer-spokesman.

1 development or exacerbation of cancerous cells.

2 38. For example, no individual prescribed to use Viagra would believe or be expected to
3 know that his use of Viagra would expose him to an increased risk of developing melanoma or
4 exacerbating the growth and/or invasion of melanocytes already present in his body.

5 39. Pfizer expected or should have expected individuals who suffered from erectile
6 dysfunction to ingest Viagra as a means to treat their condition.

7 40. Pfizer expected or should have expected physicians treating erectile dysfunction to
8 prescribe Viagra as a means to treat the condition.

9 41. The risk presented by ingesting Viagra would be present from the moment of
10 manufacture; that is, the user would not need to change or alter the drug itself or the means by
11 which it was ingested in order for the drug to carry the same risk of harm as described herein.

12 **E. Risks and Benefits of Viagra Use**

13 42. At all times relevant hereto, Viagra was useful to some members of the population;
14 namely, men diagnosed with erectile dysfunction.

15 43. Erectile dysfunction is not fatal, nor does it present any related symptoms or
16 characteristics harmful to one's physical health; however, Viagra is indicated to provide the
17 benefit of allowing men with erectile dysfunction to achieve and maintain an erection.

18 44. Viagra also encourages the development of melanoma in the body of a user, thereby
19 placing them at a significant health risk.

20 45. Pfizer manufactured, marketed and sold Viagra as a PDE5 inhibitor; however, the
21 mechanism of action that made the drug effective in treating erectile dysfunction simultaneously
22 enhanced the risk of the user developing and/or exacerbating melanoma.

23 46. At the time Viagra was formulated and manufactured, Pfizer knew or should have
24 known that the drug posed a significantly heightened risk to users, specifically through the
25 increased likelihood that those users would develop melanoma because of the chemical reactions
26 inherent to the drug's functioning.

27 47. Through the testing and formulating of Viagra, and before the initiation of the drug's
28 mass manufacture, Pfizer knew or should have known in the exercise of ordinary care that the

1 chemical reactions inherent to Viagra's mechanism of action would present a cancer-related
2 health hazard to potential future users.

3 48. The risk presented by the use of Viagra through PDE5 inhibition – a characteristic
4 inherent to the drug's potential efficacy – was unquestionably far more significant than the
5 benefit provided to its users.

6 49. Because the risk of using Viagra so greatly outweighs the benefits of such use, the
7 drug presents an unreasonably dangerous risk when used in its intended condition.

8 **F. Facts Regarding Plaintiff**

9 50. Plaintiff began pharmaceutical treatment with Viagra for erectile dysfunction in or
10 about August of 2007. It was originally prescribed by his physician, Dr. James Greene at Family
11 Practitioners of Glynn, in Brunswick, Georgia.

12 51. Plaintiff continued to fill his Viagra prescriptions and take the drug regularly until on
13 or about November 2015, or later.

14 52. On or about September 17, 2013, Dr. William Mitchell of Renue Surgery Center
15 conducted a biopsy of a skin lesion on Plaintiff's right axilla/armpit. On or about September 17,
16 2013, the biopsied skin was diagnosed as melanoma.

17 53. On or about September 17, 2013, Plaintiff underwent a deep excision of his right
18 axilla/armpit melanoma at Renue Surgery Center, in Brunswick, Georgia. On or about November
19 6, 2013, Plaintiff also underwent a second wide excision of the right axilla melanoma at Renue
20 Surgery Center, in Brunswick, Georgia. On or about December 6, 2013, Plaintiff underwent a
21 third wide excision of the right axilla melanoma at Renue Surgery Center, in Brunswick, Georgia.

22 54. Since first being diagnosed with melanoma, Plaintiff is now more susceptible to
23 development of future cancers and has had to remain vigilant in monitoring his skin for lesions.

24 55. As a direct, proximate, and legal result of Pfizer's negligence and wrongful conduct,
25 and the unreasonably dangerous and defective characteristics of the drug Viagra, Plaintiff
26 suffered severe and permanent physical and emotional injuries. His physical injuries have
27 included melanoma as well as the multiple surgeries necessitated by his skin cancer diagnosis.
28 Plaintiff has endured not only physical pain and suffering but also economic loss, including

1 significant expenses for medical care and treatment. Because of the nature of his diagnosis, he
2 will certainly continue to incur such medical expenses in the future. As a result of these damages,
3 Plaintiff seeks actual and punitive damages from Pfizer.

4 **G. Summary**

5 56. At all times relevant to this lawsuit, Pfizer engaged in the business of researching,
6 licensing, designing, formulating, compounding, testing, manufacturing, producing, processing,
7 assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising
8 for sale or selling the prescription drug Viagra in California, Plaintiff's Home Forum, and
9 throughout the United States.

10 57. For the duration of these efforts, Pfizer directed its advertising efforts to consumers
11 located across the nation, including consumers in the State of California, Plaintiff's Home Forum,
12 and throughout the United States. Such efforts were also aimed at prescribing physicians across
13 the nation, including prescribing physicians in the State of California, Plaintiff's Home Forum,
14 and throughout the United States.

15 58. At all times mentioned in this Complaint, Pfizer's officers and directors participated
16 in, authorized, and directed the production and aggressive promotion of Viagra when they knew,
17 or with the exercise of reasonable care should have known, of the risk of developing melanoma
18 associated with Viagra use. In doing so, these officers and directors actively participated in the
19 tortious conduct which resulted in the injuries suffered by many Viagra users, including Plaintiff.

20 59. Pfizer purposefully downplayed, understated and outright ignored the melanoma-
21 related health hazards and risks associated with using Viagra. Pfizer also deceived potential
22 Viagra users by relaying positive information through the press, including testimonials from
23 retired, popular United States politicians, while downplaying known adverse and serious health
24 effects.

25 60. Pfizer concealed material information related to melanoma development from
26 potential Viagra users.

27 61. In particular, Pfizer fails to mention any potential risk for melanoma development
28 and/or exacerbation associated with Viagra use in the drug label, package inserts, and the

warnings the company includes in its commercials, online and print advertisements.

62. As a result of Pfizer's advertising and marketing, and representations about its product, men in the United States, including the Plaintiff, used Viagra. If Plaintiff in this action had known the risks and dangers associated with taking Viagra, Plaintiff would have elected not to take Viagra and, consequently, would not have been subject to the increased risk of melanoma.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION **Unfair and Deceptive Trade Practices** **(Unfairness)**

63. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

64. California Business & Professions Code Section 17200 ("Unfair Competition Law" or "UCL") and applicable statutes and laws of Plaintiff's Home Forum preclude unfair competition: *i.e.*, the employment of any unlawful, unfair or fraudulent business acts or practices; and, any unfair, deceptive, untrue or misleading advertising (Cal. Bus. & Prof. Code Section 17500). This prohibition extends to any act, omission, or conduct affecting the rights of consumers.

65. Pfizer has designed and continues to design, manufacture, market, sell, and place into the stream of commerce the Viagra purchased and used in California, Plaintiff's Home Forum, and throughout the United States. Pfizer has failed and continues to fail to disclose and conceal the serious safety hazard posed by the design of Viagra—it does not warn Plaintiff or his physicians of the increased risk of developing melanoma as a result of using Viagra, and should not be purchased or used for that purpose.

66. Pfizer has been and remains obligated to disclose this material safety hazard because reasonable consumers expect Viagra to perform its only intended and reasonably expected function and purpose of allowing a user to achieve and maintain an erection. In failing to disclose this critical safety hazard, known to Pfizer but not to reasonable consumers like Plaintiff and his physicians, Pfizer engaged in and continues to engage in unfair conduct under Cal. Bus. & Prof. Code §17200 and applicable statutes and laws of Plaintiff's Home Forum. Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as particularized evidence of the pattern of omission and

1 concealment perpetrated by Pfizer against Plaintiff.

2 67. As a result of Pfizer's violations of the UCL and applicable statutes and laws of
3 Plaintiff's Home Forum, Plaintiff is entitled to appropriate equitable relief and monetary relief in
4 the form of restitution and interest. Plaintiff is also entitled to recover penalties, as well as an
5 award of attorneys' fees, costs, and expenses for prosecuting this action.

6 68. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages
7 as detailed in the Global Prayer for Relief including: compensatory damages, exemplary
8 damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and
9 such other and further relief as this Court deems just and proper.

10 **SECOND CAUSE OF ACTION**
11 **Unfair and Deceptive Trade Practices**
12 **(Fraud)**

13 69. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

14 70. California Business & Professions Code Section 17200 ("Unfair Competition Law"
15 or "UCL") and applicable statutes and laws of Plaintiff's Home Forum preclude unfair
16 competition: *i.e.*, the employment of any unlawful, unfair or fraudulent business acts or practices;
17 and, any unfair, deceptive, untrue or misleading advertising (Cal. Bus. & Prof. Code Section
18 17500). This prohibition extends to any act, omission, or conduct affecting the rights of
19 consumers.

20 71. Pfizer has designed and continues to design, manufacture, market, sell, and place into
21 the stream of commerce the Viagra purchased and used in California, Plaintiff's Home Forum,
22 and throughout the United States. Pfizer has failed and continues to fail to disclose and conceal
23 the serious safety hazard posed by the design of Viagra—it does not warn Plaintiff or his
24 physicians of the increased risk of developing melanoma as a result of using Viagra, and should
25 not be purchased or used for that purpose.

26 72. Pfizer has been and remains obligated to disclose this material safety hazard because
27 reasonable consumers like Plaintiff expect Viagra to perform its only intended and reasonably
28 expected function and purpose of allowing them to achieve and maintain an erection. In failing to
disclose this critical safety hazard, known to Pfizer but not to reasonable consumers like Plaintiff

1 or his physicians, Pfizer engaged in and continues to engage in fraudulent conduct by omission
2 under Cal. Bus. & Prof. Code §17200 and applicable statutes and laws in Plaintiff's Home Forum.
3 Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as particularized evidence of the
4 pattern of omission and concealment perpetrated by Pfizer against Plaintiff.

5 73. As a result of Pfizer's violations of the UCL and applicable statutes and laws in
6 Plaintiff's Home Forum, Plaintiff is entitled to appropriate equitable relief and monetary relief in
7 the form of restitution and interest. Plaintiff is also entitled to recover penalties, as well as an
8 award of attorneys' fees, costs, and expenses for prosecuting this action.

9 74. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages
10 as detailed in the Global Prayer for Relief including: compensatory damages, exemplary
11 damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and
12 such other and further relief as this Court deems just and proper.

13 **THIRD CAUSE OF ACTION**
14 **Unfair and Deceptive Trade Practices**
15 **(Unlawfulness)**

16 75. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

17 76. Pfizer's conduct is unlawful under the UCL because it violates Cal. Civ. Code §
18 1750, *et seq.* (hereinafter "Consumer Legal Remedies Act" or "CLRA") and applicable statutes
19 and laws in Plaintiff's Home Forum. Through omission and concealment, Pfizer has
20 misrepresented and continues to misrepresent that Viagra: (a) has characteristics, uses or benefits
21 that it does not have (Section 1770(a)(5)); and, (b) is of a particular standard, quality, or grade
22 when they are of another (Section 1770(a)(7)). Plaintiff incorporates herein paragraphs 1 and 25-
23 57, *supra*, as particularized evidence of the pattern of misrepresentation by omission perpetrated
24 by Pfizer against Plaintiff.

25 77. Were it not for Pfizer's unlawful conduct, Plaintiff would not have purchased Viagra.
26 Instead, he would have purchased safe and reliable erectile dysfunction medication fit and safe for
27 its intended purpose.

28 78. Plaintiff has and will continue to suffer injury in fact and lose money as a direct result
of Pfizer's unfair competition in that he has had to undergo multiple surgeries and will continue

1 to be required to undergo periodic skin checks to ensure against recurrence.

2 79. As a result of Pfizer's violations of the UCL and applicable statutes and laws in
3 Plaintiff's Home Forum, Plaintiff is entitled to appropriate equitable relief and monetary relief in
4 the form of restitution and interest. Plaintiff is also entitled to recover penalties, as well as an
5 award of attorneys' fees, costs, and expenses for prosecuting this action.

6 80. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages
7 as detailed in the Global Prayer for Relief including: compensatory damages, exemplary
8 damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and
9 such other and further relief as this Court deems just and proper.

10 **FOURTH CAUSE OF ACTION**
11 **(Strict Liability – Defective Design)**

12 81. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

13 82. Defendant has a duty to provide adequate warnings and instructions for Viagra, to use
14 reasonable care to design a product that is not unreasonably dangerous to users, and to adequately
15 test its product.

16 83. At all times relevant to this action, Defendant researched, designed, tested,
17 manufactured, packaged, labeled, marketed, distributed, promoted, and sold Viagra, placing the
18 drug into the stream of commerce.

19 84. At all times relevant to this action, Viagra was designed, tested, inspected,
20 manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised,
21 promoted, sold, packaged, supplied and/or distributed by Defendant in a condition that was
22 defective and unreasonably dangerous to consumers, including the Plaintiff.

23 85. Viagra is defective in its design and/or formulation in that it is not reasonably fit,
24 suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated
25 with its design and formulation.

26 86. Viagra was expected to reach, and did reach, users and/or consumers, including
27 Plaintiff, without substantial change in the defective and unreasonably dangerous condition in
28 which it was manufactured and sold.

1 87. Plaintiff used Viagra as prescribed and in the foreseeable manner normally intended,
2 recommended, promoted, and marketed by Defendant.

3 88. Viagra was unreasonably dangerous in that, as designed, it failed to perform safely
4 when used by ordinary consumers, including Plaintiff, when it was used as intended and in a
5 reasonably foreseeable manner.

6 89. Viagra was unreasonably dangerous and defective in design or formulation for its
7 intended use in that, when it left the hands of the manufacturers and/or supplier, it posed a risk of
8 serious injury which could have been reduced or avoided by the adoption of a feasible reasonable
9 alternative design. There were safer alternative methods and designs for the like product.

10 90. Viagra was insufficiently tested and caused harmful side effects that outweighed any
11 potential utility.

12 91. Viagra, as manufactured and supplied, was defective due to inadequate warnings,
13 and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results
14 of the clinical trials, testing and study.

15 92. Viagra as manufactured and supplied by the Defendant was defective due to
16 inadequate post-marketing warnings or instructions because, after Defendant knew or should have
17 known of the risk of injuries from use and/or ingestion and acquired additional knowledge and
18 information confirming the defective and dangerous nature of Viagra, Defendant failed to provide
19 adequate warnings to the medical community and the consumers, to whom Defendant was
20 directly marketing and advertising; and, further, Defendant continued to affirmatively promote
21 Viagra as safe and effective.

22 93. In light of the potential and actual risk of harm associated with the drug's use, a
23 reasonable person who had actual knowledge of this potential and actual risk of harm would have
24 concluded that Viagra should not have been marketed in that condition.

25 94. As a direct and proximate cause of the Defendant's defective design of Viagra,
26 including the lack of appropriate warnings, Plaintiff was prescribed and used the drug rather than
27 alternative erectile dysfunction therapies with better and/or similar efficacy. As a result, Plaintiff
28 has suffered significant pain, injury, harm, suffering, and economic damages incurred through

1 cancer treatment necessitated by Viagra use.

2 95. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages
3 as detailed in the Global Prayer for Relief including: compensatory damages, exemplary
4 damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and
5 such other and further relief as this Court deems just and proper.

6 **FIFTH CAUSE OF ACTION**
7 **(Strict Liability – Failure to Warn)**

8 96. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

9 97. While designing and formulating Viagra, Pfizer discovered or should have discovered
10 that the drug's mechanism of action, the inhibition of PDE5, also presented a significant risk of
11 exacerbating melanoma.

12 98. Viagra was defective and unreasonably dangerous when it left the possession of the
13 Defendant in that it contained warnings insufficient to alert consumers, including Plaintiff, of the
14 dangerous risks and reactions associated with the subject product, including but not limited to the
15 development and/or exacerbation of melanoma.

16 99. Information given by Defendant to the medical community and to consumers
17 concerning the safety and efficacy of Viagra, especially the information contained in the
18 advertising and promotional materials, did not accurately reflect the serious and potentially fatal
19 side effects.

20 100. Had adequate warnings and instructions been provided, Plaintiff would not have been
21 prescribed or taken Viagra, and would not have been at risk of the harmful side effects described
22 herein.

23 101. Neither Plaintiff, nor Plaintiff's physicians knew, nor could they have learned through
24 the exercise of reasonable care, the risks of serious injury and/or death associated with and/or
25 caused by Viagra.

26 102. Defendant knew or had knowledge that the warnings that were given failed to
27 properly warn of the increased risks of serious injury and/or death associated with and/or caused
28 by Viagra.

103. Plaintiff, individually and through his prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of the Defendant.

104. Defendant expected Plaintiff, individually and through his prescribing physician, to rely upon the information contained in the subject product's package insert and other advertising and promotional materials.

105. Defendant had a continuing duty to warn Plaintiff and his prescribing physician of the risk of development and/or exacerbation of melanoma directly associated with Viagra use.

106. Safer alternatives were available that were just as effective and without the risks posed by Viagra.

107. As a direct and proximate result of Pfizer's failure to warn Plaintiff or his physician of the significant melanoma-related risks associated with Viagra's mechanism of action, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.

108. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SIXTH CAUSE OF ACTION
(Failure to Test)

109. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

110. Through the testing and formulating of Viagra, and before the initiation of the drug's mass manufacture, Pfizer knew or should have known in the exercise of ordinary care that the chemical reactions inherent to Viagra's mechanism of action would present a cancer-related health hazard to potential future users like Plaintiff.

111. Defendant failed to adequately test the safety of Viagra.

112. Had Defendant adequately tested relative efficacy of Viagra compared with other readily available, alternative erectile dysfunction therapies and disclosed those results to the medical community and the public, Plaintiff would not have purchased and used Viagra.

113. As a direct and proximate result of Pfizer's failure to adequately test Viagra, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.

114. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SEVENTH CAUSE OF ACTION
(Negligence)

115. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

116. Defendant owed Plaintiff a duty to exercise reasonable care when designing, testing, manufacturing, labeling, marketing, advertising, promoting, distributing, and/or selling Viagra.

117. At all relevant times to this action, Defendant owed a duty to properly warn Plaintiff, physicians, consumers, and the public of the risks, dangers and adverse side effects of Viagra, including the increased risk of serious injury and death, when the drug was used as intended or in a way that Defendant could reasonably have anticipated.

118. Defendant breached its duty by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of Viagra, as set forth below.

119. Defendant failed to exercise due care under the circumstances and therefore breached this duty in numerous ways, including the following:

- a. failing to research and test Viagra properly and thoroughly before releasing the drug to the market;
- b. failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of Viagra;
- c. failing to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of Viagra which indicated serious risks associated with its use;

- d. failing to conduct adequate post-market monitoring and surveillance of Viagra;
- e. failing to conduct adequate analysis of adverse event reports;
- f. designing, manufacturing, marketing, promoting, advertising, distributing, and selling Viagra to physicians and consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Viagra and without proper instructions to avoid the harm that could foreseeably occur as a result of using the drug;
- g. failing to exercise due care when advertising and promoting Viagra;
- h. negligently continuing to manufacture, market, advertise, and distribute Viagra after Defendant knew or should have known of the risks of serious injury and/or death associated with using the drug;
- i. failing to use due care in the preparation and development of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- j. failing to use due care in the design of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- k. failing to conduct adequate pre-clinical testing and research to determine the safety of Viagra;
- l. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of Viagra, while Defendant knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of Viagra for causing serious injury and/or death in the absence of clinical trials, and that such surveillance would be necessary for a due diligence program that would alert Defendant of the need to change the drug's warnings or to withdraw it from the market altogether;
- m. failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, Plaintiff's physicians, other consumers, the medical community, and the FDA;

- n. failing to accompany Viagra with adequate and proper warnings regarding all possible adverse side effects, including serious injury (e.g., development and/or exacerbation of melanoma) associated with the use of the same and instructions on ways to safely use Viagra to avoid injury;
- o. failing to use due care in the manufacture, inspection, and labeling of Viagra to prevent the aforementioned risk of injuries to individuals who used the drug;
- p. failing to use due care in the promotion of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- q. failing to use due care in the sale and marketing of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- r. failing to use due care in the selling of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- s. failing to provide adequate and accurate training and information to the sales representatives who sold the drug;
- t. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of Viagra;
- u. failing to conduct or fund research into the development of medications of this type which would pose the least risk of causing serious injury and death as alleged herein, into the early detection of persons who might be most susceptible to such reactions, and into the development of better remedies and treatment for those who experience these tragic adverse reactions;
- v. failing to educate healthcare providers, patients, and the public about the safest use of the drug;
- w. failing to give patients and healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient; and
- x. being otherwise reckless, careless and/or negligent.

120. Despite the fact that Defendant knew or should have known that Viagra increased the risk of serious injury and/or death, Defendant continued to promote and market Viagra to doctors

1 and to consumers, including Plaintiff, when safer and more effective methods of treatment were
2 available.

3 121. As a direct and proximate result of the negligence committed by Pfizer in testing and
4 ultimately selling Viagra, Plaintiff suffered significant pain, injury, suffering, and economic
5 damages incurred through cancer treatment from melanoma caused by Viagra use.

6 122. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages
7 as detailed in the Global Prayer for Relief including: compensatory damages, exemplary
8 damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and
9 such other and further relief as this Court deems just and proper.

10 **EIGHTH CAUSE OF ACTION**
11 **(Gross Negligence)**

12 123. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

13 124. Defendant had a duty to exercise reasonable care in the warning about, design,
14 testing, manufacture, marketing, labeling, sale, and/or distribution of Viagra, including a duty to
15 ensure that Defendant's product, Viagra, did not cause users to suffer from unreasonable and
16 dangerous side effects.

17 125. Defendant failed to exercise reasonable care in the warning about, design, testing,
18 manufacture, marketing, labeling, sale, and/or distribution of Defendant's product, Viagra, in that
19 Defendant knew or should have known that taking Viagra caused unreasonable and life-
20 threatening injuries, as alleged herein.

21 126. Defendant was grossly negligent under the circumstances and breached its duty of
22 care in numerous ways, including the following:

- 23 a. failing to test Viagra properly and thoroughly before releasing the drug to the
- 24 market;
- 25 b. failing to analyze properly and thoroughly the data resulting from the pre-
- 26 marketing tests of Viagra;
- 27 c. failing to report to the FDA, the medical community, and the general public
- 28 those data resulting from pre- and post-marketing tests of Viagra which

1 indicated risks associated with its use;

- 2 d. failing to conduct adequate post-market monitoring and surveillance of Viagra;
- 3 e. failing to conduct adequate analysis of adverse event reports;
- 4 f. designing, manufacturing, marketing, advertising, distributing, and selling
- 5 Viagra to consumers, including Plaintiff, without an adequate warning of the
- 6 significant and dangerous risks of Viagra and without proper instructions to
- 7 avoid the harm which could foreseeably occur as a result of using the drug;
- 8 g. failing to exercise due care when advertising and promoting Viagra;
- 9 h. recklessly continuing to manufacture, market, advertise, and distribute Viagra
- 10 after Defendant knew or should have known of the risks of serious injury and/or
- 11 death associated with using the drug;
- 12 i. failing to use due care in the preparation and development of Viagra to prevent
- 13 the aforementioned risk of injuries to individuals when the drug was ingested;
- 14 j. failing to use due care in the design of Viagra to prevent the aforementioned
- 15 risk of injuries to individuals when the drug was ingested;
- 16 k. failing to conduct adequate pre-clinical testing and research to determine the
- 17 safety of Viagra;
- 18 l. failing to conduct adequate post-marketing surveillance and exposure studies to
- 19 determine the safety of Viagra, while Defendant knew or should have known
- 20 that post-marketing surveillance would be the only means to determine the
- 21 relative risk of Viagra for causing serious injury and death as alleged herein in
- 22 the absence of clinical trials, and that such surveillance would be necessary for
- 23 a due diligence program that would alert Defendant to the need to change the
- 24 drug's warnings or to withdraw it from the market altogether;
- 25 m. failing to completely, accurately and in a timely fashion, disclose the results of
- 26 the pre-marketing testing and post-marketing surveillance and testing to
- 27 Plaintiff, her doctors, other consumers, the medical community, and the FDA;
- 28 n. failing to accompany Viagra with proper warnings regarding all possible

- adverse side effects associated with the use of the same;
- o. failing to use due care in the manufacture, inspection, and labeling of Viagra to prevent the aforementioned risk of injuries to individuals who used the drug;
- p. failing to use due care in the promotion of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- q. failing to use due care in the sale and marketing of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- r. failing to provide adequate and accurate training and information to the sales representatives who sold the drug;
- s. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of Viagra;
- t. failing to conduct or fund research into the development of medications of this type which would pose the least risk of causing such serious injury and death, as alleged herein, into the early detection of persons who might be most susceptible to such reactions, and into the development of better remedies and treatment for those who experience these tragic adverse reactions;
- u. failing to educate healthcare providers and the public about the safest use of the drug;
- v. failing to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient; and
- w. was otherwise grossly negligent.

127. Although Defendant knew, or recklessly disregarded, the fact that Defendant's product, Viagra, caused serious and potentially fatal side effects, Defendant continued to market Viagra to consumers, including Plaintiff, without disclosing these side effects including the risks of serious injury and/or death.

128. Defendant knew and/or consciously or recklessly disregarded the fact that consumers such as Plaintiff would suffer injury as a result of Defendant's failure to exercise reasonable care as described above.

129. Defendant knew of, or recklessly disregarded the defective nature of Defendant's product, Viagra, as set forth herein, but continued to design, manufacture, market, and sell Viagra, so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by Viagra.

130. As a direct and proximate result of Pfizer's gross negligence, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.

131. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

NINTH CAUSE OF ACTION
(Negligence Per Se)

132. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

133. At all times herein mentioned, Defendant had an obligation not to violate the law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the manufacture, design, formulation, compounding, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting, sale, warning, and post-sale warning and other communications of the risks and dangers of Viagra.

134. By reason of its conduct as alleged herein, Defendant violated provisions of statutes and regulations, including, but not limited to, the following:

- a. Defendant violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 352, by misbranding Viagra;
- b. Defendant failed to follow the "[g]eneral requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. § 201.56;
- c. Defendant failed to follow the "[s]pecific requirements on content and format

of labeling for human prescription drugs” in violation of 21 C.F.R. § 201.57;
and

d. Defendant advertised and promoted Viagra in violation of 21 C.F.R. § 202.1;
and

e. Defendant violated 21 C.F.R. § 201.57(e) by failing to timely and adequately
change the Viagra label to reflect the evidence of an association between Viagra
and the development and/or exacerbation of melanoma suffered by Plaintiff.

These statutes and regulations impose a standard of conduct designed to protect consumers
of drugs, including Plaintiff. Defendant’s violations of these statutes and regulations constitute
negligence per se.

135. As a direct and proximate result of Defendant’s statutory and regulatory violations,
Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through
cancer treatment from melanoma caused by Viagra use.

136. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages
as detailed in the Global Prayer for Relief including: compensatory damages, exemplary
damages, and punitive damages, together with interest, the costs of suit and attorneys’ fees, and
such other and further relief as this Court deems just and proper.

TENTH CAUSE OF ACTION
(Breach of Express Warranty)

137. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

138. At all times relevant hereto, Pfizer expressly represented and warranted to Plaintiff
and his healthcare providers, by and through statements made by Pfizer or its authorized agents or
sales representatives, orally and in publications, package inserts and other written materials
intended for physicians, medical patients and the general public, that Viagra is safe, effective, and
proper for its intended use.

139. Defendant breached expressed warranties with respect to Viagra in the following
particulars:

a. Defendant represented through its labeling, advertising, marketing materials,

1 seminar presentations, publications, notice letters, and regulatory submissions
2 that Viagra was safe, and fraudulently withheld and concealed information
3 about the substantial risks of serious injury and/or death associated with using
4 Viagra;

5 b. Defendant represented that Viagra was as safe, and/or safer than other
6 alternative medications and fraudulently concealed information that
7 demonstrated that Viagra was not safer than alternatives available on the
8 market; and

9 c. Defendant represented that Viagra was more efficacious than other alternative
10 medications and fraudulently concealed information regarding the true efficacy
11 of the drug.

12 140. Viagra does not conform to Defendant's express representations because its
13 mechanism of action, the inhibition of the PDE5 enzyme, also increases the risk of the
14 development and/or exacerbation of melanoma.

15 141. At all relevant times, Viagra did not perform as safely as an ordinary consumer would
16 expect when used as intended or in a reasonably foreseeable manner.

17 142. Plaintiff, Plaintiff's physicians, other consumers, and the medical community relied
18 upon Defendant's express warranties, resulting in Plaintiff's ingestion of the drug.

19 143. As a direct and proximate result of the breach of warranty committed by Pfizer,
20 Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through
21 cancer treatment from melanoma caused by Viagra use.

22 144. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages
23 as detailed in the Global Prayer for Relief including: compensatory damages, exemplary
24 damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and
25 such other and further relief as this Court deems just and proper.

26 **ELEVENTH CAUSE OF ACTION**
27 **(Breach of Implied Warranty)**

28 145. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

146. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted, and sold Viagra.

147. At all relevant times, Defendant intended that Viagra be used in the manner that Plaintiff in fact used it.

148. Defendant impliedly warranted Viagra to be of merchantable quality, safe and fit for the use for which Defendant intended it, and Plaintiff in fact used it.

149. Defendant was aware that consumers, including Plaintiff, would use Viagra to achieve and maintain an erection; which is to say that Plaintiff was a foreseeable user of Defendant's product Viagra.

150. Defendant knew, or had reason to know, that Plaintiff's physician would rely on Defendant's judgment and skill in providing Viagra for its intended use.

151. Plaintiff and his physician reasonably relied upon the skill and judgment of Defendant as to whether Viagra was of merchantable quality, safe and fit for its intended use.

152. The drug was expected to reach and did in fact did reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

153. Defendant breached various implied warranties with respect to Viagra including the following particulars:

- a. Defendant represented through its labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that Viagra was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using Viagra;
- b. Defendant represented that Viagra was as safe, and/or safer than other alternative medications and fraudulently concealed information that demonstrated that Viagra was not safer than alternatives available on the market; and
- c. Defendant represented that Viagra was more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy

1 of the drug.

2 154. In reliance upon Defendant's implied warranty, Plaintiff used Viagra as prescribed
3 and in the foreseeable manner normally intended, recommended, promoted, and marketed by
4 Defendant.

5 155. Viagra was neither safe for its intended use nor of merchantable quality, as had been
6 implicitly warranted by Pfizer, in that Viagra's mechanism of action – the inhibition of PDE5 –
7 inherently presented a significant increase in the user's risk of developing and/or exacerbating
8 melanoma.

9 156. Defendant breached its implied warranty to Plaintiff in that Viagra is unreasonably
10 dangerous, defective, and unfit for the ordinary purposes for which Viagra was used. It was not of
11 merchantable quality, safe and fit for its intended use, or adequately tested.

12 157. As a direct and proximate result of the falsity of the warranties implicated by Pfizer's
13 actions and omissions, Plaintiff suffered significant pain, injury, suffering, and economic
14 damages incurred through cancer treatment from melanoma caused by Viagra use.

15 158. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages
16 as detailed in the Global Prayer for Relief including: compensatory damages, exemplary
17 damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and
18 such other and further relief as this Court deems just and proper.

19 **TWELFTH CAUSE OF ACTION**
20 **(Fraudulent Misrepresentation and Concealment)**

21 159. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

22 160. Defendant intentionally and fraudulently misrepresented to consumers and
23 physicians, including Plaintiff, Plaintiff's physicians and the public in general, that Viagra had
24 been tested and found to be safe, well-tolerated and/or more efficacious than alternative
25 medications and/or methods of erectile dysfunction therapy and that Viagra's benefits outweighed
26 its risks when used as instructed, when, in fact, Defendant knew, or should have known, and
27 fraudulently concealed that Viagra is dangerous to patients and that the benefits of its use are far
28 outweighed by the risks for Plaintiff and many others.

1 161. At all relevant times, Defendant knew of the use for which Viagra was intended and
2 expressly and/or impliedly warranted its drug was of merchantable quality and safe and fit for
3 such use.

4 162. Defendant had sole access to material facts concerning the dangers and unreasonable
5 risks of Viagra.

6 163. Defendant's superior knowledge and expertise, its relationship of trust and confidence
7 with doctors and the public, its specific knowledge regarding the risks and dangers of Viagra and
8 its intentional dissemination of promotional and marketing information about Viagra for the
9 purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose
10 and provide all material information about the risks and harms associated with the drug.

11 164. Defendant made false affirmative representations, omissions and/or fraudulently
12 concealed material adverse information regarding the dangers, risks, safety, benefits, utility and
13 effectiveness of Viagra in order to induce Plaintiff, Plaintiff's physicians, and the public in
14 general to rely upon such representations and to use Viagra. By failing to disclose important
15 safety and injury information and suppressing material facts about Viagra to Plaintiff, Plaintiff's
16 physicians and the public in general, Defendant further led Plaintiff and Plaintiff's physicians to
17 rely upon the safety of Viagra.

18 165. Defendant had a duty to disclose such information, arising from Defendant's actions
19 of making, marketing, promoting, labeling, distributing and selling pharmaceutical products to
20 Plaintiff and others.

21 166. Defendant's false representations and concealments were fraudulently made, in that
22 Viagra in fact caused injury, was unsafe, and the benefits of its use were far outweighed by the
23 risk associated with use thereof.

24 167. Defendant committed acts of intentional misrepresentation and intentional
25 concealment by suppressing material facts relating to the dangers and substantial risks of serious
26 injuries and/or death associated with, and caused by, the use of Viagra.

27 168. Defendant made such false representations, omissions and concealments with the
28 intent or purpose that Plaintiff and Plaintiff's physicians would rely upon such representations,

1 leading to the use of Viagra by Plaintiff.

2 169. Defendant made fraudulent affirmative misrepresentations and omissions and
3 fraudulent concealments of material facts regarding the safety and effectiveness of Viagra and of
4 the dangers and risks of injuries associated with Viagra, including:

- 5 a. Defendant fraudulently represented through its labeling, advertising, marketing
6 materials, seminar presentations, publications, notice letters, and regulatory
7 submissions that Viagra had been adequately tested and found to be safe and
8 effective for erectile dysfunction, and fraudulently concealed information about
9 the substantial risks of serious injury and/or death associated with using Viagra;
10 and
- 11 b. Defendant fraudulently represented that Viagra was as safe and/or safer and/or
12 more efficacious than other alternative erectile dysfunction therapies, and
13 fraudulently concealed information that demonstrated that Viagra was not safer
14 and/or more efficacious than alternatives available on the market.

15 170. Defendant knew, had reason to know, or should have known that these
16 representations and actively concealed adverse information were false, and that Viagra had
17 defects and was unreasonably dangerous. Yet, Defendant willfully, wantonly, and recklessly
18 disregarded its obligation to provide truthful representations regarding the safety and risk of
19 Viagra to consumers, including Plaintiff, and to the medical community.

20 171. Defendant did not have adequate proof upon which to base such representations, and
21 in fact, given Defendant's knowledge about Viagra's pharmacology and reported adverse events,
22 Defendant knew or should have known that these representations, omissions and/or concealments
23 were false and fraudulent. Specifically, Defendant knew of, possessed evidence and/or had reason
24 to know that Viagra had defects and was unreasonably dangerous, causing the development
25 and/or exacerbation of melanoma, as detailed herein.

26 172. Defendant's misrepresentations were made with the intent that physicians and
27 patients, including Plaintiff, would rely upon them and were made with the intent of defrauding
28 and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the

1 sale of Viagra.

2 173. Plaintiff, Plaintiff's physicians, and others, did rely upon and/or were induced by the
3 misrepresentations, omissions and/or active concealment of the dangers of Viagra to the detriment
4 of the Plaintiff.

5 174. Defendant's fraudulent representations and concealments evince its callous, reckless,
6 willful, and depraved indifference to the health, safety, and welfare of consumers, including
7 Plaintiff.

8 175. In selecting treatment, Plaintiff's physicians and Plaintiff relied on and were induced
9 by Defendant's misrepresentations concerning the dangers of Viagra.

10 176. As detailed herein, Defendant made these fraudulent misrepresentations, omissions
11 and concealments through statements and comments to the press, labeling, advertising, marketing
12 and promotion materials, seminar presentations, publications, Dear Doctor letters and regulatory
13 submissions.

14 177. Plaintiff and the treating medical community did not know that the representations,
15 omissions, and/or concealments made by Defendant were false and were justified in reasonably
16 relying upon Defendant's representations.

17 178. Had Defendant not fraudulently misrepresented and concealed such information,
18 Plaintiff would not have ingested Viagra and suffered resulting harm.

19 179. Defendant made the aforesaid representations and concealments intentionally and in
20 the course of Defendant's business as designers, manufacturers, and distributors of Viagra despite
21 having no reasonable basis for the assertion that these representations were true, without having
22 accurate or sufficient information concerning the aforesaid representations and/or knowing these
23 representations were false. Defendant was aware that without such information it could not
24 accurately make the aforesaid representations.

25 180. At the time Defendant made the aforesaid representations and at the time Plaintiff
26 received Viagra, Plaintiff, Plaintiff's physicians, and the public in general reasonably believed
27 them to be true. At the time that Plaintiff received Viagra, Defendant failed to adequately inform
28 Plaintiff and/or his prescribing doctors that Viagra use increased the risk of the development

1 and/or exacerbation of melanoma, despite Defendant being in possession of such evidence.
2 Plaintiff received no adequate warnings, either written or verbal, that Viagra caused these side
3 effects, and relied on these omissions and concealments.

4 181. As a direct and proximate consequence of Defendant's fraudulent misrepresentations,
5 omissions and intentional concealment of material facts, upon which Plaintiff reasonably relied,
6 Plaintiff sustained significant pain, injury, harm, suffering, and economic damages incurred
7 through cancer treatment from melanoma caused by Viagra use.

8 182. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages
9 as detailed in the Global Prayer for Relief including: compensatory damages, exemplary
10 damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and
11 such other and further relief as this Court deems just and proper.

12 **THIRTEENTH CAUSE OF ACTION**
13 **(Negligent Misrepresentation and Concealment)**

14 183. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

15 184. At all relevant times, Defendant designed, tested, manufactured, packaged, marketed,
16 distributed, promoted, and sold Viagra.

17 185. At all relevant times, Defendant knew of the use for which Viagra was intended and
18 expressly and/or impliedly warranted that the drug was of merchantable quality and safe and fit
19 for such use.

20 186. Defendant's superior knowledge and expertise, its relationship of trust and confidence
21 with doctors and the public, its specific knowledge regarding the risks and dangers of Viagra and
22 its intentional dissemination of promotional and marketing information about Viagra for the
23 purpose of maximizing its sales, each gave rise to the affirmative duty to disclose and provide all
24 material information about the risks and harms associated with the drug.

25 187. Defendant recklessly, and/or negligently represented to Plaintiff, Plaintiff's
26 physicians, and other persons and professionals whom Defendant knew would rely, that Viagra
27 was safe to ingest and that the utility of this product outweighed any risk in use for their intended
28 purposes.

188. Defendant recklessly and/or negligently failed to disclose to Plaintiff, and others, important safety and efficacy information, thereby suppressing material facts about the drug, while having a duty to disclose such information, which duty arose from its actions of making, marketing, promoting, distributing and selling pharmaceutical products to Plaintiff and others.

189. Defendant led Plaintiff to rely upon the safety of the product in its use.

190. The false representations of the Defendant were recklessly and/or negligently made in that Viagra in fact caused injury, was unsafe, and the benefits of its use were far outweighed by the risk associated with use thereof.

191. Defendant committed acts of reckless and/or negligent misrepresentation and reckless and/or negligent concealment by suppressing material facts relating to the dangers and injuries associated with, and caused by, the use of Viagra.

192. Defendant knew or should have known that its representations and/or omissions were false. Defendant made such false, negligent and/or reckless representations with the intent or purpose that Plaintiff and Plaintiff's physicians would rely upon such representations, leading to the use of Viagra by Plaintiff.

193. Defendant recklessly and/or negligently misrepresented, and/or omitted information with respect to Viagra in the following particulars:

- a. Defendant represented through its labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that Viagra was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using Viagra;
- b. Defendant represented that Viagra was as safe and/or safer than other alternative erectile dysfunction therapies and fraudulently concealed information, which demonstrated that Viagra was not safer than alternatives available on the market; and
- c. Defendant represented that Viagra was more efficacious than other alternative erectile dysfunction therapies and fraudulently concealed information, regarding the true efficacy of the drug.

1 194. Defendant made affirmative misrepresentations and recklessly and/or negligently
2 omitted material adverse information regarding the safety and effectiveness of Viagra.

3 195. Defendant made these misrepresentations and/or omissions at a time when Defendant
4 knew or had reason to know that Viagra had defects and was unreasonably dangerous and was not
5 what Defendant had represented to the medical community, the FDA and the consuming public,
6 including Plaintiff.

7 196. Defendant omitted, suppressed, and/or concealed material facts concerning the
8 dangers and risk of injuries associated with the use of Viagra including, serious injury and death.
9 Furthermore, Defendant was willfully blind to, ignored, downplayed, avoided, and/or otherwise
10 understated the serious nature of the risks associated with the use of Viagra in order to increase
11 sales.

12 197. Defendant's misrepresentations and/or omissions were undertaken by Defendant with
13 an intent that doctors and patients, including Plaintiff, rely upon them.

14 198. Defendant's misrepresentations and/or omissions were undertaken with the intent of
15 defrauding and/or deceiving Plaintiff, other consumers, and the medical community to induce and
16 encourage the sale of Viagra.

17 199. Defendant's misrepresentations and/or omissions evinced the Defendant's callous,
18 reckless, willful, and depraved indifference to the health, safety, and welfare of consumers,
19 including Plaintiff.

20 200. Plaintiff's physician and Plaintiff relied on and were induced by Defendant's
21 misrepresentations, omissions, and/or active concealment of the dangers of Viagra in selecting
22 treatment.

23 201. Plaintiff and Plaintiff's physicians did not know that the representations made by
24 Defendant were false and were justified in relying upon Defendant's representations.

25 202. Had Plaintiff been aware of the increased risk of side effects associated with Viagra
26 and the relative efficacy of Viagra compared with other readily available alternative erectile
27 dysfunction therapies, Plaintiff would not have taken Viagra.

28 203. As a direct and proximate consequence of Defendant's misrepresentations, Plaintiff

1 sustained injuries and damages alleged herein including specifically those alleged herein.

2 204. Plaintiff relied on the misrepresentations made by Pfizer in purchasing and using
3 Viagra.

4 205. Plaintiff's reliance on Pfizer's misrepresentations was justified because such
5 misrepresentations were made by entities that were in a position to know of and disclose any
6 potentially harmful information concerning the use of Viagra.

7 206. If Plaintiff had known of the information concealed by Pfizer regarding the
8 melanoma-related risks posed by Viagra, Plaintiff would not have purchased and subsequently
9 used Viagra.

10 207. As a direct and proximate result of the negligent misrepresentations by Defendant,
11 Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through
12 cancer treatment from melanoma caused by Viagra use.

13 208. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages
14 as detailed in the Global Prayer for Relief including: compensatory damages, exemplary
15 damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and
16 such other and further relief as this Court deems just and proper.

17 **FOURTEENTH CAUSE OF ACTION**
18 **(Fraud and Deceit)**

19 209. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

20 210. At all times relevant hereto, Pfizer conducted a sales and marketing campaign to
21 promote the sale of Viagra and willfully deceive Plaintiff, Plaintiff's healthcare providers, and the
22 general public as to the benefits, health risks, and consequences of using Viagra.

23 211. While conducting its sales and marketing campaign, Pfizer knew that Viagra is
24 neither safe nor fit for human consumption; that using Viagra is hazardous to health; and that
25 Viagra has a propensity to cause serious injuries, such as those suffered by Plaintiff.

26 212. From the time the company first marketed and distributed Viagra until the present,
27 Pfizer willfully deceived Plaintiff by concealing from him, his healthcare providers, and the
28 general public the risks and dangers concerning the use of Viagra.

213. Pfizer intentionally concealed and suppressed the facts concerning Viagra's melanoma-related risks with the intent to defraud potential consumers, as Pfizer knew that healthcare providers would not prescribe Viagra, and consumers like Plaintiff would not use Viagra, if they were aware of the dangers posed by using Viagra.

214. As a direct and proximate result of Pfizer's fraudulent and deceitful conduct, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.

215. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

FIFTEENTH CAUSE OF ACTION
(Willful, Wanton, and Malicious Conduct)

216. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

217. Pfizer directly or indirectly, maliciously and wantonly made, created, manufactured, designed, tested, labeled, supplied, packaged, distributed, promoted, marketed, advertised, warned, and/or sold Viagra.

218. Pfizer breached its duty and was wanton and malicious in its actions, misrepresentations, and omissions in that it:

- a. failed to test Viagra properly and thoroughly before releasing the drug to the market;
- b. failed to analyze properly and thoroughly the data resulting from the pre-marketing tests of Viagra;
- c. failed to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of Viagra which indicated risks associated with its use;
- d. failed to conduct adequate post-market monitoring and surveillance of Viagra;
- e. failed to conduct adequate analysis of adverse event reports;

- 1 f. designed, manufactured, marketed, advertised, distributed, and sold Viagra to
- 2 consumers, including Plaintiff, without an adequate warning of the significant
- 3 and dangerous risks of Viagra and without proper instructions to avoid the harm
- 4 which could foreseeably occur as a result of using the drug;
- 5 g. failed to exercise due care when advertising and promoting Viagra;
- 6 h. willfully and wantonly continued to manufacture, market, advertise, and
- 7 distribute Viagra after Defendant knew or should have known of the risks of
- 8 serious injury and/or death associated with using the drug;
- 9 i. willfully and wantonly failed to use due care in the preparation and
- 10 development of Viagra to prevent the aforementioned risk of injuries to
- 11 individuals when the drug was ingested;
- 12 j. willfully and wantonly failed to use due care in the design of Viagra to prevent
- 13 the aforementioned risk of injuries to individuals when the drug was ingested;
- 14 k. failed to conduct adequate pre-clinical testing and research to determine the
- 15 safety of Viagra;
- 16 l. failed to conduct adequate post-marketing surveillance and exposure studies to
- 17 determine the safety of Viagra, while Defendant knew or should have known
- 18 that post-marketing surveillance would be the only means to determine the
- 19 relative risk of Viagra for causing such serious injury and death as alleged
- 20 herein in the absence of clinical trials, and that such surveillance would be
- 21 necessary for a due diligence program that would alert Defendant to the need to
- 22 change the drug's warnings or to withdraw it from the market altogether;
- 23 m. failed to completely, accurately and in a timely fashion, disclose the results of
- 24 the pre-marketing testing and post-marketing surveillance and testing to
- 25 Plaintiff, Plaintiff's physicians, other consumers, the medical community, and
- 26 the FDA;
- 27 n. failed to accompany Viagra with proper warnings regarding all possible adverse
- 28 side effects associated with the use of the same;

- o. willfully and wantonly failed to use due care in the manufacture, inspection, and labeling of Viagra to prevent the aforementioned risk of injuries to individuals who used the drug;
- p. willfully and wantonly failed to use due care in the promotion of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- q. willfully and wantonly failed to use due care in the sale and marketing of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- r. willfully and wantonly failed to use due care in the selling of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- s. failed to provide adequate and accurate training and information to the sales representatives who sold the drug;
- t. failed to provide adequate and accurate training and information to healthcare providers for the appropriate use of Viagra;
- u. failed to conduct or fund research into the development of medications of this type which would pose the least risk of causing serious injury and death as alleged herein, into the early detection of persons who might be most susceptible to such reactions, and into the development of better remedies and treatment for those who experience these tragic adverse reactions;
- v. failed to educate healthcare providers and the public about the safest use of the drug;
- w. failed to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient; and
- x. otherwise behaved willfully, wantonly, and maliciously.

219. Pfizer knew or should have known that Viagra was unreasonably dangerous and could cause serious injuries, including death.

220. As a direct and proximate result of the wanton and malicious acts and omissions of

Pfizer, the Plaintiff sustained injuries and damages alleged herein.

221. As a direct and proximate result of Pfizer's willful, wanton and malicious conduct, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.

222. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SIXTEENTH CAUSE OF ACTION
(Unjust Enrichment)

223. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

224. At all times relevant to this action, Defendant designed, advertised, marketed, promoted, manufactured, distributed, supplied, and/or sold Viagra.

225. Plaintiff purchased Viagra for the purpose of achieving and maintaining an erection.

226. Defendant has accepted payment from Plaintiff for the purchase of Viagra.

227. Plaintiff did not receive the safe and effective pharmaceutical product for which Plaintiff intended to purchase.

228. It is inequitable and unjust for Defendant to retain this money because the Plaintiff did not in fact receive the product Defendant represented Viagra to be.

229. Based on the foregoing, Plaintiff is entitled to equitable relief against Defendant on account of its unjust enrichment.

230. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

VI. PUNITIVE DAMAGES

231. Prior to the manufacturing, sale, and distribution of Viagra, Pfizer knew that said medication was in a defective condition as previously described herein, and knew that those who

1 were prescribed the medication would experience and had already experienced severe physical,
2 mental, and emotional injuries.

3 232. Pfizer, through its officers, directors, managers, and agents, knew that Viagra
4 presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and, as
5 such, Pfizer unreasonably subjected consumers of said drugs to risk of injury or death from using
6 Viagra.

7 233. Pfizer and its agents, officers, and directors intentionally proceeded with the
8 manufacturing, sale, and distribution and marketing of Viagra knowing these actions would
9 expose persons to serious danger in order to advance the company's market share and profits.

10 234. The acts, conduct, and omissions of Pfizer, as alleged throughout this Complaint,
11 were willful and malicious.

12 235. Pfizer's unconscionable conduct warrants an award of exemplary and punitive
13 damages against the company.

14 **VII. GLOBAL PRAYER FOR RELIEF**

15 **WHEREFORE**, Plaintiff prays judgment against Pfizer as follows:

- 16 A. Declare, adjudge and decree the conduct of Defendant as alleged herein to be unlawful;
- 17 B. Actual, compensatory, punitive and/or exemplary damages in such amount to be
18 determined at trial and as provided by applicable law;
- 19 C. Costs of suit, including reasonable attorneys' fees, and expenses as provided by law; and
- 20 D. Other, further, and different relief as the nature of the case may require or as may be
21 determined to be just, equitable, and proper by this Court.

22 **VIII. DEMAND FOR JURY TRIAL**

23 Plaintiff demands a trial by jury.
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1 Dated: April 1, 2016

ROBINS KAPLAN LLP

2
3 By: /s/ Gary L. Wilson

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